K002510

OCT 1 8 2000

510(k) Summary - SmartLens® Dynamic Observing Tonometer

Submitter:

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Name of Device:

Trade Name: SmartLens®
Common Name: SmartLens® Dynamic Observing Tonometer
Generic Name: Tonometer, AC-powered
Product Code: HKX
Regulation: 21 CFR §886.1930

Predicate Device:

Blood Flow Analyzer, manufactured by Paradigm Medical Industries, Inc., 1772 West 2300 South, Salt Lake City, UT 84119 and found substantially equivalent by FDA on June 17, 1997 under 510(k) # K970887.

Device Description:

SmartLens® is comprised of the following parts: Probe, Marker Button, Base Station and a Database Package for a standard PC. SmartLens® is a diagnostic medical device to be used by ophthalmologists only.

In contrast to a conventional eye tonometer the contact surface to measure the intra-ocular pressure is fully transparent and lens-shaped.

System Components

The core of the system is the **Probe**, for use on the patient's eye. Major elements are a lens with built-in pressure sensor, a battery and an electronic data transmission function. The pressure measurement system consists of a pressure-sensitive membrane in the center of the lens, a pressure propagation bore and a pressure sensor, which is located outside the transparent part of the lens. The data transmission function converts pressure data into a digital modulated HF signal and transmits the latter via a built-in antenna to the Base Station.

The **Marker Button** can be placed freely in a convenient working position.
The design of the Marker Button is similar to the Probe's; the difference is that is has a switch function instead of a lens and pressure sensor.

With this switch, marks can be put on the pressure curve during the examination. The data transformation function transfers the data pulses into a digital HF signal and transmits it, via an internal antenna. Visual observations of the inner eye can thus be correlated with the associated pressure value.

The **Base Station** can be placed close to the examination location; it has the following functions:

- Docking position for the Probe and the Marker to charge the internal battery and to pre-heat the Probe.
- Receive and store the measured data.
- Calculate the Baseline Pressure (intra-ocular pressure without support pressure from lens on the eye) from the profile of the measured data (online).
- Receive and store data from the Marker Button.
- Show the results on a display screen.
- Control the proper functioning while the system is used (correct application etc.).
- Warn the user, through acoustical signals, in case of malfunction.
- Communication and data exchange with the PC to store and analyse recorded pressure curves.
- Learning function: allows the user to control proper application of the probe on the eye by means of acoustical signals from the Base Station.

The Database Software Package for the PC includes following functions:

- Communication and data exchange with the Base Station
- Display and analysis of measured data
- Edit of patient's private data and comments to measured data
- Archive patient's and measured data and comments in a database
- Printing of all data on any standard printer

Usually the SmartLens® is operated in combination with a slit lamp, which is basically standard equipment for every ophthalmologist. A standard PC is required to analyse and archive data, which can be printed by any usual printer. This equipment is not part of the SmartLens®.

Dimensions / Weight

	Dimensions	Weight
Base Station	198 x 147 x 115 mm	900 g
Probe	42 x 38 mm	24 g
Marker Button	42 x 38 mm	16 g
Power Supply	79 x 74 x 29 mm	85 g
Carry case	360 x 270 x 140 mm	
SmartLens® System in case		3.5 kg

Power Supply

Primary operating voltage	110 – 240 VAC
Primary frequency	47 – 63 Hz
Primary current	200 mA
Secondary voltage	9 VDC
Secondary current	1.5 A
Power consumption	max. 14 W
Operating voltage of rechargeable battery	7.2 V NIMH

The power supply is auto-sensing. Voltage adjustments are not required.

System Variations

SmartLens® can be supplied with or without the Database Software Package.

Intended Use:

The intended use of the SmartLens® Dynamic Observing Tonometer is to continuously measure and record short-term fluctuations of intraocular pressure (IOP) with simultanuous observation of the pressure dependent morphological changes of internal structures in the eye (optic nerve, vasculature, ciliary body).

Technical Comparison to Predicate Device:

Item	Smartlens	Blood Flow Analyser
Diagnostic procedure	Non-invasive measurement of intraocular pressure (IOP), ocular pulse amplitude (OPA) and simultanuous ophthalmoscopy / gonioscopy. Option to make online markings during measurement. Option to provoke higher pressure in the eye. Patient sitting at slit lamp or in sitting or supine position without slit lamp.	Non-invasive measurement of intraocular pressure and pulse amplitude with patient in position of sitting, standing or supine
Sensor	Pressure sensor integrated in a hand-held gonioscopic contact lens.	Remote sensor probe with gas powered sensing element.
Sensor tip material	Polyester membrane	Polyurethane membrane
Lens	Lens is pre-heated to body temperature by filtered air.	N/A
Data display	Base Station and/or computer monitor provides numerical readout and graphical display.	Console monitor provides numerical readout and graphical display.
Data recording	After (optional) data transmission to evaluation software on computer, possibility to print full report in chart and data regarding pressure (mmHg) and time (seconds) on a standard printer*.	Dot Matrix Printer or laser printer or plotter with output for chart recorder (vertical axis=pressure (mmHg), horizontal axis=time (seconds)).
Data storage	Maximum storage capacity in Base Station is 10 records. When data are transferred to SmartLens Database on PC, storage capacity is related to PC memory.	Computer memory system.
Data transmission	Radio transmission (lens to Base Station) Response by cable (Base Station to PC).	Cable
Calibration	Calibration value is set during end test before delivery. Check on pressure-sensitivity data during pre-heating. Calibration is checked during periodical service program.	External calibration verifier standard (air gauge with plunger/silicone diaphragm system).

* Planned Extension: printing of chart/data direct from Base Station (4thQ. 2000)

Performance:

Components/Assemblies: System consisting of Basestation/Probe/Marker including operational SW plus PC-Software for diagnosis, database and system control.

This test plan summarizes type certification tests, production test plans (PP) and production test procedures (PA), which have been established to guarantee the quality and safe operation of the product.

List of Documents: (filenames are not translated)

Production Test Plans (PP):
Production Test Procedures (PA):
PP001.011.901
PA001.011.902
PA001.013.903
PA001.012.903
PA001.001.003
PA001_Init_SmL
PP001_Software
PP001_Service

Reports:
B001_mech_therm_Typenprüfung_MK
B001_Pumpe_Filter_BS
B001_Biologische_Verträglichkeit_MK
B001_Desinfektionstest_MK
B001_EMV_SmL
B001_Sicherheit_SmL

Test Protocols:
PPR001_RF_SmL
PPR001.011.015

Distribution of Documents:
· Test plan PP001.001.003: 1 copy in ODC Device Master File
· Type Certification Tests: 1 copy in ODC Device Master File
(Originals in ODC safe)

List of Tests

	Probe / Marker		System	Base Station
Type Certification Tests (performed once during certification)	Biological compatibility test according DIN 30993-1 (B001_Biologische_Verträglichkeit_MK)		EMC test according ETS 300 683, ETS 300 330, ETS 300 320, EN60601-1-2 (B001_EMV_SmL)	Service life test of air filter and pump (B_001_Pumpe_Filter_BS)
	Desinfection test (B001_Desinfektionstest_MK)		Electrical hazard test according EN 60601-1, IEC 601-1 (B001_Sicherheit_SmL)	Heater test (PP001_Software)
	Mechanical and thermal type certification (B001_mech_therm_Typenprüfung_MK)		RF-Interoperability test Basestat./Probe/Marker (PPR001_RF_SmL)	
	Test of battery against surcharge and short circuit (PPR001.011.015)		Test and validation of operational software according testplan (PP001_Software)	
Production Tests	Tests during production of probe assemblies (PP001.011.901)			Tests during basestation assembly (PA001.012.903)
	Test during probe assembly (PA 001.011.902)	Test during marker assembly (PA 001.013.903)		
Final Tests			Test of system performance when linked to PC (PA 001.001.002)	
			General system functionality test (PA001_Init_SmL)	
Maintenance / Repairs	Exchange of battery (PP001_Service) Exchange of battery (PP001_Service)			
	Calibration of probe (PA_Eichung, PP001_Service)			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2000

ODC Ophthalmic Development Co. AG
c/o Mr. Kevin Walls, President
Regulatory Associates, Inc.
777 S. Wadsworth Blvd.
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Re: K002510
Trade Name: SmartLens® Dynamic Observing Tonometer
Regulatory Class: II
Product Code: 86 HKX
Regulation: 886.1930
Dated: October 11, 2000
Received: October 16, 2000

Dear Mr. Walls:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):

Device Name: SmartLens® Dynamic Observing Tonometer

Indications for Use: SmartLens® Dynamic Observing Tonometer is intended to continuously measure and record short-term fluctuations of intraocular pressure (IOP) with simultaneous observation of the pressure dependent morphological changes of internal structures in the eye (optic nerve, vasculature, ciliary body).

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002510

Prescription Use X
(Per 21 CFR 801.109)